

REMARKS/ARGUMENTS

STATUS OF THE CLAIMS

Claims 1-120 are pending. Applicant has amended Claims 12, 38, 41, and 43-48. Applicant respectfully requests reconsideration of pending Claims 1-120 in light of the following remarks.

CLAIM REJECTION – 35 U.S.C. § 112

Claim 12 stands rejected under 35 U.S.C. § 112, second paragraph. Applicant has amended Claim 12 to recite “said means for actuating said electrode to create an electrical field comprising a means for transmitting to said electrode an electrical impulse having an amplitude of from about two to about six volts.” Amended Claim 12 now only recites a single “means for transmitting” step. Applicant respectfully requests withdrawal of the rejection to Claim 12.

CLAIM REJECTIONS – 35 U.S.C. § 102

Independent Claim 37

Claim 37 stands rejected under U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,381,499 issued to Taylor et al. (“Taylor”).

Claim 37 specifies “a first electrode positioned on the neck of said patient” and “a second electrode positioned on the neck of said patient in spaced apart relation to said first electrode.”

Taylor discloses a method of facilitating coronary surgery on the beating heart. *Taylor*, Abstract. Taylor discloses the use of minimally-invasive clips that provide precise and efficient electrical contact with the vagus nerve. *Id.* at col. 5, lines 49-51. Taylor notes that although the description is made relative to the specific clip configurations of Figs. 1-5, “the underlying features... and the attendant functions and advantages thereof, are equally applicable to the clips and probes of other configurations.” *Id.* at col. 5, lines 51-57. The clips of Taylor are considered “minimally invasive” because the clips “bite gently into the nerve to provide positive electrical

contact therewith as well as to prevent the clip from falling off the nerve.” *Id.* at col. 7 lines, 12-16. Taylor further discloses that “it is important that electrical contact and electrical stimulation be made only with the vagus nerve and not the surrounding vessels, tissues, etc.” *Id.* at col. 7, lines 16-19.

The Examiner argues that, “although the clips shown are invasive, they may alternatively be non-invasive (col. 5, lines 23-26).” *Office Action*, mailed August 4, 2006, page 3. Applicant respectfully traverses this statement. The non-invasive clips disclosed by Taylor are non-invasive with respect to the vagus nerve, not with respect to the patient’s neck. Taylor states that the non-invasive clips “are described below with reference to the figures.” *Taylor*, col. 5, lines 25-26. However, all of the electrode clip constructions illustrated and described by Taylor must be inserted invasively into the neck or into another area of the patient to gain direct access to the vagus nerve. As a result, Taylor does not disclose that the clips can be placed on a neck of a patient, without being in direct electrical contact with the vagus nerve.

Accordingly, Taylor does not disclose “a first electrode positioned on the neck of said patient,” and “a second electrode positioned on the neck of said patient in spaced apart relation to said first electrode” as specified by Claim 37. Therefore, independent Claim 37 and dependent Claims 39 and 40 are allowable.

Dependent Claims 39 and 40

Claims 39 and 40 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Taylor. Claims 39 and 40 depend from Claim 37 and are therefore allowable for the reasons discussed with respect to Claim 37. Claims 39 and 40 also specify additional patentable subject matter not specifically discussed herein.

Independent Claim 41

Claim 41 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Taylor.

Amended Claim 41 specifies “a first electrode positioned on the neck of said patient,” “a second electrode positioned on the neck of said patient in spaced apart relation to said first electrode,” and “means for actuating at least one of said electrodes to create an electrical field operative to actuate said at least one of said electrodes to stimulate said vagus nerve for a period of between about fifteen seconds and about ninety seconds.”

As discussed with respect to Claim 37, Taylor does not disclose electrodes positioned on the neck of the patient. Rather, Taylor only discloses electrodes that bite into the vagus nerve or clip directly onto the vagus nerve.

With respect to electrode actuation, Taylor discloses that a suitable electrical stimulating device is used to apply electric energy to the vagus nerve. *Taylor*, col. 2, lines 18-19. Taylor discloses the use of electrical energy in the form of a continuous electrical pulse train of 10 seconds or less. *Id.* at col. 2, lines 20-21. Taylor also discloses that the electrical stimulation applied to the nerve may be derived by a continuous five second train of electrical pulses. *Id.* at col. 5, lines 34-36. However, Taylor does not disclose using the electrodes to stimulate the vagus nerve for any periods of time greater than 10 seconds.

Accordingly, Taylor also does not disclose “means for actuating at least one of said electrodes to create an electrical field operative to actuate said at least one of said electrodes to stimulate said vagus nerve for a period of between about fifteen seconds and about ninety seconds,” as specified by Claim 41. Therefore, independent Claim 41 and dependent Claim 42 are allowable.

Dependent Claim 42

Claim 42 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Taylor. Claim 42 depends from Claim 41 and is therefore allowable for the reasons discussed with respect to

Claim 41. Claim 42 also specifies additional patentable subject matter not specifically discussed herein.

Independent Claim 43

Claim 43 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Taylor.

Amended Claim 43 specifies “a first electrode positioned on the neck of said patient,” “a second electrode positioned on the neck of said patient in spaced apart relation to said first electrode,” and “means for actuating at least one of said electrodes to create an electrical field comprising a means for transmitting an impulse to said at least one of said electrodes at a frequency of between about thirty Hertz and about five hundred Hertz.”

As discussed with respect to Claim 37, Taylor does not disclose electrodes positioned on the neck of the patient. Rather, Taylor only discloses electrodes that bite into the vagus nerve or clip directly onto the vagus nerve.

With respect to electrode actuation, Taylor discloses the use of electrical energy in the form of a continuous five second train of electrical pulses at 25 Hertz. *Taylor*, col. 5, lines 34-36. Taylor also discloses that the electrical energy may be a 50 milli-Hertz current. *Id.* at col. 2, line 23. However, Taylor does not disclose applying electrical pulses at any frequency other than 25 Hertz or 50 milli-Hertz.

Accordingly, Taylor also does not disclose “means for actuating at least one of said electrodes to create an electrical field comprising a means for transmitting an impulse to said at least one of said electrodes at a frequency of between about thirty Hertz and about five hundred Hertz,” as specified by Claim 43. Therefore, independent Claim 43 and dependent Claim 44 are allowable.

Dependent Claim 44

Claim 44 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Taylor. Claim 44 depends from Claim 43 and is therefore allowable for the reasons discussed with respect to Claim 43. Claim 44 also specifies additional patentable subject matter not specifically discussed herein.

Independent Claim 46

Claim 46 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Taylor.

Amended Claim 46 specifies “a first electrode positioned on the neck of said patient,” “a second electrode positioned on the neck of said patient in spaced apart relation to said first electrode,” and “means for actuating said electrode to create an electrical field comprising a means for transmitting electrical impulses having a duration of at least 0.2 msec for actuating said electrode.”

As discussed with respect to Claim 37, Taylor does not disclose electrodes positioned on the neck of the patient. Rather, Taylor only discloses electrodes that bite into the vagus nerve or clip directly onto the vagus nerve.

With respect to electrode actuation, Taylor discloses the use of electrical energy having a pulse width of 0.1 milliseconds. *Taylor*, col. 5, lines 35-37. However, Taylor does not disclose using electrical stimulation having any pulse width other than 0.1 milliseconds.

Accordingly, Taylor also does not disclose “means for actuating said electrode to create an electrical field comprising a means for transmitting electrical impulses having a duration of at least 0.2 msec for actuating said electrode,” as specified by Claim 46. Therefore, independent Claim 46 is allowable.

Independent Claim 47

Claim 47 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Taylor.

Amended Claim 47 specifies “a first electrode positioned on the neck of said patient,” “a second electrode positioned on the neck of said patient in spaced apart relation to said first electrode,” and “means for actuating said electrode to create an electrical field comprising a means for transmitting to said electrode an electrical impulse having an amplitude of from about twenty-five to about forty volts.”

As discussed with respect to Claim 37, Taylor does not disclose electrodes positioned on the neck of the patient. Rather, Taylor only discloses electrodes that bite into the vagus nerve or clip directly onto the vagus nerve.

With respect to electrode actuation, Taylor discloses the use of electrical energy having an amplitude of 20 Volts. *Taylor*, col. 5, lines 35-37. However, Taylor does not disclose an electrical stimulation having any amplitude other than 20 Volts.

Accordingly, Taylor also does not disclose “means for actuating said electrode to create an electrical field comprising a means for transmitting to said electrode an electrical impulse having an amplitude of from about twenty-five to about forty volts,” as specified by Claim 47. Therefore, independent Claim 47 is allowable.

ALLOWABLE SUBJECT MATTER

Applicant appreciates the indication of allowable subject matter in Claims 38, 45, and 48, and the allowance of Claims 1-11, 13-36, and 49-120. Applicant has amended Claims 38, 45, and 48 into independent form by incorporating the limitations of the base claim and any intervening claims. Applicant respectfully requests allowance of Claims 38, 45, and 48.

CONCLUSION

In light of the above, Applicant respectfully requests reconsideration and allowance of pending Claims 1-120.

Respectfully submitted,


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